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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,886	12/07/2005	Alan Cuthbertson	PN0380	1550

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1618	

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09/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,886	CUTHBERTSON ET AL.	
	Examiner	Art Unit	
	D L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/7/05 & 7/9/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *2,3,7 and 9-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-6, and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/24/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 12/7/05 wherein the specification and claims 4-7 were amended.

Note: Claims 1-11 are pending.

APPLICANT'S INVENTION

2. The instant invention is directed to pharmaceuticals comprising Formula I and uses thereof.

RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election without traverse of Group I (claims 1, 4-6, and 8) in the reply filed on 7.9.09 is acknowledged. Thus, the restriction is deemed proper and is made FINAL.

WITHDRAWN CLAIMS

4. Claims 2, 3, 7, and 9-11 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

112 SECOND PARAGRAPH REJECTIONS

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 4-6, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4-6, and 8: The claims as written are ambiguous because of independent claim 1. Specifically, in claim 1, line 5, the phrase 'L denotes and optional

linker' is vague and indefinite because if the linker is optional and is absent, it is unclear what definition is assigned to the variable L. In addition, in claim 1, line 6, the phrase 'Z denotes a group' appears. This phrase is vague and indefinite because it is unclear what Z group(s) Applicant is claiming that are compatible with the instant invention. In claim 1, line 10, the phrase 'mimetic of Arg' is vague and indefinite because it is unclear what specific compounds Applicant is claiming that are equivalent to Arg. In claim 1, lines 11-12, the phrase 'and wherein the residues Val and Ile at position 3 and 5 respectively may optionally be replace with amino acids capable of forming a bridge' is vague and indefinite. Specifically, the phrase is unclear because it is unclear what specific amino acids Applicant is claiming that when they replace Val and Ile will generate the desired bridge. In other words, it is unclear what type of bridge (i.e., disulfide bond') Applicant is claiming that is compatible with the instant invention. In addition, based on the use of 'capable of' in the sentence, the formation of and actual bond is not required since 'capable of' language only requires that a component have the ability to form a bridge. Also, in claim 1, lines 5 and 13, the claim is ambiguous because Applicant has defined the variable Z in two different ways. Thus, one cannot ascertain which definition actual applies to the instant invention. Furthermore, in claim 1, lines 14-15, the phrase 'M where present denotes an imagable moiety capable of detection either directly or indirectly in a diagnostic imaging procedure is confusing. Specifically, the phrase is confusing because it is unclear what imagable moieties Applicant is claiming that are compatible with the peptide X1-X2-Val-Tyr-Ile-His-Pro-X3.

Hence, since independent claim 1 is indefinite, all claims depending thereon (claims 4-6 and 8) are also vague and indefinite.

Claim 5, lines 5 and 14: The claim as written is ambiguous because Applicant has defined the variable Q in two different ways. Thus, it is unclear what the actual definition of Q is in the instant invention.

Claim 5, line 9: The variables Y and X are not defined in the claim. Did Applicant intend Y to be Y_1? As for the variable X, it is unclear how Applicant is defining the variable.

Claim 6: The claim contains improper Markush terminology. Specifically, Markush terminology requires the use of 'closed' language. As a result, the phrase 'selected from the group consisting of' is often used. However, in Applicant's claim 5, line 3, the term 'comprising' appears which is 'open' terminology. Applicant is respectfully requested to review MPEP 803.02.

102 REJECTIONS

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Griswold et al (US Patent No. 5,824,696).

Griswold et al disclose angiotensin II receptor antagonist medicaments that are useful in the treatment of chronic inflammatory diseases (see entire document,

especially, abstract; column 1, lines 9-11). In Figure 1, the species [125I](Sar1, Ile8) angiotensin II is disclosed (see also column 16, Table 1). In column 6, lines 15-16, the sequence Asp-Arg-Val-Tyr-Ile-His-Pro-Phe (SEQ ID No. 1) is disclosed. This sequence fulfills the requirements of the instant invention when X3 = Phe; X1 = Asp; and X2 = Arg. In column 15, lines 32-63, it is disclosed that the pharmaceutical formulation may be prepared in various carriers. Thus, both Applicant and the cited prior art disclose radiolabeled pharmaceuticals comprising the sequence X1-X2-Val-Tyr-Ile-His-Pro-X3.

103 REJECTIONS

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 4-6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Archer et al (WO 03/006070) in view of Griswold et al (US Patent No. 5,824,696).

Archer et al disclose improved chelate conjugates that are complexed with biological targeting molecules (see entire document, especially, abstract). In the background, Archer et al disclose diaminedioximes chelating agents that are complexed with 99mTc (page 1, lines 5-14). Archer disclose another chelate, page 4, lines 1-19). The biological moiety that may be attached to the chelators are those having 3-100 amino acid residues (page 4, lines 21-24). Preferably the biological targeting moieties are 3-20 amino acid residues (pages 4-5, bridging paragraph). Also, Archer et al disclose addition chelator conjugates that may be used with their invention (page 9, lines 19-25; page 17, lines 10-24). Various radiometals may be attached to the chelator conjugate (page 12, lines 14-21). While Archer et al disclose various peptides containing 3-100 amino acid residues, the reference fails to specifically disclose the peptide X1-X2-Val-Tyr-Ile-His-Pro-X3.

Griswold et al (see discussion above) fail to disclose various chelators that may be used with the instant invention.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Archer et al using the teachings of Griswold et al and generate a peptide -chelate conjugate encompassed by Formula I of the instant invention for the reasons set forth below. Archer et al disclose that it is known in the art to conjugate various chelators to peptides having 3-100 amino acid residues. Archer et a disclose that an advantage to using their chelates is that the chelates conjugated to the biological targeting moiety results in meta complexes with radiometals that are useful as radiopharmaceuticals. In addition, Archer et al like, Grisword et al disclose various medical uses for their radiopharmaceutical. Hence, a skilled artisan would be motivated to using the teachings of the references combined because it is well known in the art to use select peptides for desired medical procedures, as well as select chelators having improved properties. Hence, the inventions disclose overlapping subject matter.

PRIORITY DOCUMENT

13. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

COMMENTS/NOTES

14. Applicant is respectfully requested to modify the title of the instant invention to be more descriptive of the instant invention.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D L. Jones whose telephone number is (571)272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D L. Jones/
Primary Examiner
Art Unit 1618

September 24, 2009